## REMARKS

This amendment is responsive to the Office Action of November 6, 2001. Reconsideration of claims 1-22 and consideration of new claim 23 are respectfully requested.

## The Office Action

**Claims 1-22** were rejected under 35 U.S.C. § 103(a) as being unpatentable over **Minerovic, et al.** (U.S. Patent No. 5,997,814) in view of **Ignacio, et al.**, (U.S. Patent No. 6,287,518).

## The Present Application

The present application is directed to a single use package for holding a powdered composition. An indicator is located on a porous portion of the package and exhibits a detectable change on exposure to the decontaminant in the solution as it is formed. The package is designed to be placed in a well or other sterilant-preparation region separate from the sterilizing compartment or region. The indicator provides assurance that the decontaminant solution being formed in the well reaches the appropriate concentration for sterilization, high level disinfection, or the like. Powdered peracetic acid precursors, such as perborate, tend to break down when stored or shipped under improper conditions or with age. For example, high temperatures dampness, and other conditions can degrade the perborate or other peracetic acid precursors. The failure of the indicator to make the prescribed color changes indicates that the ingredients in the package failed to generate on effective antimicrobical solution, whether due to age, dampness or high temperatures, during storage or shipping or other reasons. Stated conversely, the correct color change assures the operator that the package functioned properly.

Proper functioning of the package does not necessarily assure that sterilization was achieved in the decontamination chamber. Rather, conditions in the decontamination chamber (other than proper/improper functioning of the package) affect the success of a sterilization process.

**The References of Record**

The **Minerovic, et al.** patent is directed to a one-use, two-compartment cup for holding dry reagents. A first reagent is held in a cup formed from a porous material. A second reagent is held separately from the first reagent in an outer cup. A water permeable top cover seals the outer cup and traps the reagents in their respective cups. A detachable base wall **58** is formed at the base of the outer cup.

The **Ignacio, et al.** patent discloses a sterilization monitor for monitoring a sterilization process. As is typical in sterilization processes, the monitor is placed in the chamber **as close as possible to the items to be sterilized**, either directly on an instrument to be sterilized, or on packaging used to wrap the instrument. By placing the monitor as close as possible to the items, the monitor will indicate whether the item was subject to sterilizing conditions. The monitor includes a substrate, such as strip of blotter paper, a dye, which changes color when exposed to a peracid, and a halogen source. The substrate may have an adhesive which allows it to be used as a label or tape.

**Ignacio** provides no motivation to locate a sterilization monitor remote from the sterilized item, at which remote location it would not be a reliable indicator that the item was sterilized.

**The Claims Distinguish Patentably Over th Refer nces of Record**

**Claim 1** has been amended and calls for a single-use package holding a powdered composition which forms a solution of an anti-microbial decontaminant when mixed with water. The package includes an indicator which exhibits a detectable change on exposure to the decontaminant in the solution. Such an indicator provides the operator with an immediate indication whether the package functioned properly to generate the decontaminant solution. The indicator can also provide visual assurance prior to a sterilization cycle that a fresh cup is being used.

The references of record, alone or in combination, do not disclose or fairly suggest such a single-use package with an indicator of successful package operation. As the Examiner acknowledges, **Minerovic, et al.** does not teach using an indicator which exhibits a detectable change on exposure to the decontaminant in the solution. Moreover, Minerovic, et al. provides no motivation for including such an indicator. As indicated in the background section of the Minerovic, et al. patent, a "two-compartment cup ensures sterilization with a reproducible, pre-measured dose of reagents" (col. 2, lines 1-3). **Minerovic** does not disclose a means for checking whether the contents of the cup are good and not degraded. At best, **Minerovic** might have a "last use" date on the packaging to show its age. But such a date is more apt than a color change to be overlooked by an operator and it provides no indication if the package was subject to inappropriate shipping or storage conditions.

(1) **Ignacio, et al.** teaches placing a sterilization monitor within a sterilization chamber directly on the item or its wrap during a sterilization process to show whether the item was sterilized. Contrary to the Examiner's assertion, (2) there is no suggestion of placing the indicator on a single-use package which holds an antimicrobial agent. Nor is there any motivation for doing so. (3) To the contrary,

Ignacio, et al. teaches against placing indicators as the sterilant source in favor of placing the indicator in the chamber, attached to the items to be sterilized or its packaging, preferably, attached to a medical instrument or a sterile wrap therefor. This package, such as a Tyvek pouch, is permeable to a peracid vapor. It does not, however, hold a powdered composition which forms a solution of an anti-microbial decontaminant when mixed with water, as is now claimed, or even any similar sterilant concentrate. As is conventional with sterilization indicators, Ignacio, et al. places the monitor as close to the item being sterilized as possible, so that it is subjected to the same sterilizing environment as the item. The **Ignacio** monitor does NOT indicate whether the item to which it is attached has operated properly.

Unlike the vapor-permeable packages used by Ignacio, et al. for holding items to be sterilized, which are positioned **within** the chamber, packages containing antimicrobial agents are typically positioned in a well, or other holding device remote from the items, such as **outsid** the chamber as disclosed by Minerovic, et al. To place the indicator of Ignacio, et al. on such a package, which is typically located well away from the items being sterilized, would defeat the object of Ignacio's invention, which is to monitor sterilizing conditions around the medical instruments within the chamber during sterilization. Thus, Ignacio teaches away from placing an indicator on a single use package, such as that of Minerovic.

Further, if one were to use the monitor of Ignacio, et al. with Minerovic, et al. one would place an indicator in the chamber, in close association with the items being sterilized. Neither Minerovic nor Ignacio provide any motivation to attach the Ignacio monitor to the antimicrobial concentrate package of Minerovic.

Contrary to the conventional positioning of a sterilization indicator in a chamber, as close to the

instruments as possible, the present applicants have found that mounting an indicator on a single use package can have several advantages. First, it can ensure that an indicator is used each time a sterilization process occurs, since the operator will typically insert a fresh antimicrobial concentrate package prior to the start of the cycle. Second, the indicator is less likely to be lost, for example, by being washed out of the chamber during the cycle, or by being returned to the shelves, along with the medical instruments. Neither these unexpected benefits, nor the problems which they are able to overcome, are taught or fairly suggested by the references of record.

Accordingly, it is submitted that claim 1 and claims 2-7, 9-14, 16-18, and 22 dependent thereon, differ patentably and unobviously over the references of record.

**Claim 8** focuses on the location of the indicator on a single use package for holding a dry composition which forms an anti-microbial solution when mixed with water. The package includes a side wall and a bottom wall across a lower portion of the sidewall. A top cover defines a porous portion which is impermeable to the dry composition but is permeable to water and to the solution. An indicator on the top cover exhibits a detectable change on exposure to the anti-microbial solution.

None of the references of record, alone or in combination, discloses or fairly suggests such a single-use package with an indicator on a top cover. As discussed for claim 1, **Minerovic, et al.** provides no motivation for using an indicator on a single use package. Thus, there is no motivation for combining the references of Minerovic, et al. and **Ignacio, et al.**, much less this advantageous placement of the indicator. Ignacio, et al. places a monitor on an item to be sterilized, or on its vapor-permeable packaging, not on its sterilant source. This is a very different package from the presently claimed package holding a dry composition which forms an anti-microbial solution.

Ignacio's package surrounds the item during sterilization, and thus is placed within the chamber. In many sterilization processes, particularly steam processes, the items are wrapped with a steam/gas permeable package which is microbe impermeable, e.g. a gauze wrap, a Tyvek™ envelope or pouch, etc. This enables the items to be removed and stored without recontamination from airborn microbes. Ignacio's monitor is specifically placed on the item package in order to be exposed to equivalent sterilization conditions to the item. Ignacio thus teaches away from placing a monitor on a package as presently claimed, which holds the sterilant.

The present inventors have found that a single-use package with an indicator on a top cover allows sterilant concentrations to be measured in anti-microbial solution which has already been circulated through a chamber. Thus, the indicator is generally exposed to a minimum anti-microbial concentration of the recirculating solution.

Accordingly, it is submitted that claim 8 differs patentably and unobviously over the references of record.

**Claim 15** calls a for a package for holding an anti-microbial concentrate which forms an anti-microbial solution when mixed with water. The package releases anti-microbial concentrate at a selected time in an anti-microbial cycle. The package includes a porous portion which is impermeable to the anti-microbial concentrate but is permeable to water and to the solution. An indicator on the porous portion exhibits a detectable color change when exposed to a preselected minimum concentration of the decontaminant for a preselected minimum period of time to indicate the formulation of an anti-microbial solution capable of effecting anti-microbial decontamination.

None of the references of record, alone or in combination, discloses or fairly suggests such a package. The **Minerovic, et al.** patent provides no motivation for employing any indicator on the sterilants supply package.

**Ignacio, t al.** does not disclose or fairly suggest placing an indicator on a package which supplies an anti-microbial at a selected time in an anti-microbial cycle. Rather, Ignacio, et al. places a monitor on a package that encloses a medical instrument.

Accordingly, it is submitted that claim 15 differs patentably and unobviously over the references of record.

**Claim 19** calls for an anti-microbial system including a well for receiving a single use package. The package includes a cup which holds an anti-microbial concentrate. The cup includes an inlet. A porous portion on the inlet is permeable to water and to an anti-microbial solution formed from the anti-microbial concentrate and the water. An indicator on the porous portion exhibits a detectable change on exposure to a decontaminant in the solution. A source of water and a chamber are provided. Recirculating anti-microbial solution passes over the indicator.

The references of record do not fairly suggest such a system. The **Minerovic, et al.** patent provides no motivation for employing an a indicator in the sterilization system shown in Figure 1 of the patent. It is assumed that the reproducible, premeasured dose will ensure sterilization. **Ignacio, et al.** does not suggest putting an indicator on a porous portion at an inlet of a single use package. Rather, the indicator is placed on packaging for a medical instrument.

Accordingly, it is submitted that claim 19 differs patentably and unobviously over the references of record.

**Claim 20** calls for a package for releasing an anti-microbial composition into a flowing liquid. A side wall has a first opening at a first end and a second opening at a second end such that the liquid flows through the first opening into the package and out through the second opening. A layer of porous material spans one of the first and second openings such that the liquid flows through the porous

material layer. An anti-microbial source is disposed within the package for releasing the anti-microbial composition into the flowing liquid to form an anti-microbial solution. An indicator on the porous material layer changes color in response to contact with the anti-microbial solution, a degree of color change varying in accordance with (i) a concentration of an anti-microbial agent in the solution contacting the indicator, and (ii) a duration that the solution contacts the indicator such that the degree of color change of the indicator is indicative of duration of contact and the concentration of the anti-microbial agent in the contacting solution.

The references of record do not disclose or fairly suggest such a package. **Minerovic, et al.** provides no motivation for using an indicator. **Ignacio, et al.** teaches placing a sterilization monitor on a medical device or its packaging, i.e., as close to the instrument as possible. Thus, **Ignacio, et al.** teaches away from placing an indicator on a package holding an anti-microbial source.

Accordingly, it is submitted that claim 20 differs patentably and unobviously over the references of record.

**Claim 21** calls for a method including flowing water through a cartridge containing a composition to form a decontaminant solution from the composition and the water, the cartridge including a porous region impregnated with an indicator. The indicator exhibits a preselected detectable change when contacted with a decontaminant solution and at a concentration of a decontaminant in the solution sufficient to effect decontamination of items.

The references of record do not suggest such a method. **Minerovic, et al.** provides no motivation for using any indicator. **Ignacio, et al.** teaches away from using an indicator on a cartridge which contains a composition for forming a decontaminant solution.

Accordingly, it is submitted that claim 21 distinguishes patentably and unobviously over the references of record.

New **Claim 23** emphasizes that a well for a single-use package is connected with a chamber by a fluid line. **Ignacio, et al.** requires the sterilization monitor to be placed in the sterilization chamber. Ignacio thus teaches away from placing an indicator in a well, which may be well away from the chamber.

Accordingly, it is submitted that claim 23 distinguishes patentably and unobviously over the references of record.

**CONCLUSION**

For the reasons set forth above, it is submitted that claims 1-23 distinguish patentably and unobviously over the references of record. An early allowance of all claims is earnestly solicited.

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**CERTIFICATE OF MAILING**

I hereby certify that this **AMENDMENT C** in connection with U.S. Patent Application **Serial No. 09/314,497** is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Box Amendment, Washington, DC 20231, on February 1, 2002.

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**VERSION OF CLAIMS WITH MARKINGS TO SHOW CHANGES MADE**
**January 30, 2002**



Please amend claims 1 and 19, as follows:

1. (Twice Amended) A single-use package [for] holding a powdered composition which forms a solution of an anti-microbial decontaminant when mixed with water and for releasing the composition when the package is opened or when the composition dissolves and passes through a porous portion of the package, the package comprising:

a porous portion which is impermeable to the powdered composition but is permeable to water and to the solution; and,

an indicator on the porous portion which exhibits a detectable change on exposure to the decontaminant in the solution.

19. (Twice Amended) An anti-microbial system comprising:

a well for receiving a single use package, the package including:

at least one cup which holds an anti-microbial concentrate, the cup including an inlet,

a porous portion affixed to the cup inlet which is permeable to water and to an anti-microbial solution formed from the anti-microbial concentrate and the water, and

an indicator on the porous portion which exhibits a detectable change on exposure to a decontaminant in the solution;

a source of water connected with the well for mixing with the anti-microbial concentrate and forming the anti-microbial solution;

a microbial decontamination chamber connected with the well for receiving the anti-microbial solution, the well, the porous region, and the chamber forming a recirculating fluid flow path for the anti-microbial solution, whereby the recirculating anti-microbial solution passes over the indicator.

Please add new claim 23, as follows:

23. (New) An anti-microbial system comprising:

a well for receiving a single use package, the package including:

at least one cup which holds an anti-microbial source for forming an antimicrobial solution when mixed with water,

a porous portion connected to the cup and being permeable to water and to an anti-microbial solution formed from the anti-microbial source and the water, and

an indicator carried on the porous portion which exhibits a detectable change on exposure to a decontaminant in the anti-microbial solution;

a source of water connected with an inlet to the well for mixing with the anti-microbial source and forming the anti-microbial solution;

a microbial decontamination chamber for receiving the anti-microbial solution from an outlet from the well;

a fluid line connecting the chamber with the well outlet;

the well, the fluid line, and the chamber forming a recirculating fluid flow path for the anti-microbial solution through the porous region, whereby the recirculating anti-microbial solution passes over the indicator.